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HISH S. MAJZOUB, M.D.

December 6, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. **97N-484S**

Dear Sir/Madam:

I would like to voice my objection for the proposed FDA regulation that would regulate allografts as medical devices. It would be extremely hard for us, the surgeons, who utilize allografts to treat patients with spine fractures and spine injuries and also degenerative cervical spine disease if we have to use allografts should they become regulated as medical devices. Such as move would definitely hinder the treatment of patients and also make it very hard to obtain the desire allografts to treat patients with such diseases. We feel that such a proposal is ill advised and not necessary as the allograft should be treated as bone tissue and should not be regulated as medical devices.

The proposed regular would impose significant hardship on the surgeon and patient and we feel that this move is not in the best interest of the medical community and also the patients in general.

Sincerely yours,

H. S. Majzoub, M. D.

HSM/cm

97N-484S C90

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